



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Timothy J. O'Brien et al. Group Art Unit: 1642
Serial No.: 09/965,738 Examiner: Peter J. Reddig
Filed: September 27, 2001 Docket No.: 110.018US1
Title: REPEAT SEQUENCES OF THE CA125 GENE AND THEIR USE FOR
DIAGNOSTIC AND THERAPEUTIC INTERVENTIONS

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Timothy J. O'Brien declare and say as follows:

1. I am an inventor of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 09/965,738.
2. I have reviewed the Office Action mailed March 22, 2007 in relation to the above-identified patent application. I make this declaration in support of the patentability of the claims of U.S. Patent Application Serial No. 09/965,738.
3. I am a Professor in the Department of Obstetrics and Gynecology at the University of Arkansas for Medical Sciences, Little Rock, AR. I received a Ph.D. degree from the University of Illinois.
4. My co-inventors and I have sequenced the cDNA encoding CA125 by cloning and sequencing amplified cDNA fragments encoding portions of CA125, as is described in this patent application. We have aligned overlapping contiguous sequences to determine the overall sequence of the very long CA125 cDNA and the encoded CA125 polypeptide.
5. We were able to determine overlapping sequences of all portions of the reported CA125 cDNA sequence. Because of the overlapping sequences of the cDNA fragments, we were able to align the fragments in order to assemble the CA125 sequence reported as SEQ ID NO:162. Because of the confirmation provided by overlapping sequences, we have a high degree of confidence that SEQ ID NO:162 is a correct protein

sequence of CA125 over the entire length of SEQ ID NO:162. We feel we have taken all steps reasonably possible to verify that SEQ ID NO:162 is correct.

6. Since filing the application, we have cloned and sequenced other CA125 cDNA fragments from both normal and cancerous ovarian tissue samples. All of these newer CA125 cDNA sequences are consistent with SEQ ID NO:162, and none of the newer sequences changes our conclusion that SEQ ID NO:162 is a correct protein sequence for CA125. We have later found additional amino terminal sequence of CA125 that extends the amino terminus of CA125 beyond the amino terminus of SEQ ID NO:162. This is reported in copending U.S. patent applications 10/475,117 and 10/715,066. But all evidence indicates SEQ ID NO:162 is a correct partial sequence of CA125.

7. Although we now know that SEQ ID NO:162 is only a partial sequence of CA125, an isolated recombinant polypeptide comprising SEQ ID NO:162 is useful for, among other purposes, raising antibodies that specifically bind to CA125.

8. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Furthermore, these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and with knowledge that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 6/15/07 By: Timothy J O'Brien
Timothy J O'Brien

Subscribed and sworn before me this 15th day of June 2007, in the county of Pulaski, in the state of Arkansas.

Amanda G. Richards
NOTARY PUBLIC

